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Design consideration for ACL implants based on mechanical loading

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This study aims to understand and estimate the forces while the anterior cruciate ligament (ACL) is subjected to loading during stair negotiation. 9 healthy subjects were recruited and asked to negotiate stairs while their motion was captured. An OpenSim model was developed to estimate the ACL length from kinematic data. The forces were estimated using a force/displacement relationship. The peak ACL force was 0.416 ± 0.089 N/BW and was recorded at full extension of the knee while the participants were descending stairs. The forces experienced by the right and left ACL of women were highly significant compared to ACL forces in men and the ACL forces in old people were significantly higher than in younger people. These forces will be used as boundary conditions in a novel finite element model (FEM) to estimate tensile and shear stress levels in the ACL to gain design information to create a tissue engineered ACL implant. The CIRP-Biomanufacturing conference promotes the exchange of knowledge on biodesign and biofabrication in order to develop novel medical devices for improving quality of life. This work is relevant to the conference since it contributes to a better understanding of the mechanical behavior of ACL throughout its range of motion and it is the starting point for the design and manufacture of new ACL implants.

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Keywords: Anterior cruciate ligament (ACL); stairs negotiation; in vivo kinematics; knee model; ACL forces; ACL strain.

1. Introduction

Ligament injuries are among the most common health problems. It has been estimated that the incidence of injuries to knee ligaments could be at 2/1000 people per year, of which 90% involve the anterior cruciate ligament (ACL) and the medial collateral ligament (MCL) [1]. In the United States more than 200,000 patients are diagnosed with ACL ruptures every year, of which 175,000 cases of ACL injuries require surgery, whose cost has been estimated at \$1 billion annually [2].

The ACL is an intraarticular ligament with poor healing properties; therefore ACL injuries often require a surgical reconstruction. Currently, both biological and synthetic scaffolds are used to repair ligaments, although both of them exhibit serious limitations. Tissue Engineering is presented as an alternative eliminating donor-site morbidity and rejection, and restoring the structure and physiological natural tissue functions using a long-term biodegradable scaffold with

similar biological and mechanical properties to natural ligaments [3].

Many researchers are developing new tissue engineered ligament and tendon implants. However, regarding to mechanical characterization, only material properties such as Young's modulus, ultimate tensile strain or tensile stress at yield are considered to discriminate if the scaffold has the appropriate characteristics to be implanted.

As far as the authors know, no connection has been created between mechanical behavior at all ranges of motion and design and development of ligaments based on tissue engineering.

The novelty of this project is trying to understand how this ligament behaves while different activities are performed to study the failure mechanisms on the ACL and to be able to design improved implants according to the forces experienced on these natural fibrous connective tissues.

These forces were estimated through a motion capture system in combination with a musculoskeletal model developed in OpenSim software capable to determine the *in*

in vivo ACL length at each moment and with it the ACL strain and force.

To date many studies with cadaveric knees have been performed [4] for different reasons, for determining parameters such as length or area at the attachment sites of the ligament and for understanding its behaviour under mechanical loading. Although the information provided by these studies is very valuable, they have limitations reproducing the *in vivo* mechanical behaviour of the ACL. Other studies use video and motion capture [5, 6] to understand the ACL injury mechanisms; however they do not assess the ACL length or strain, they merely study joint kinematics. Several experiments have been conducted using strain gauges [7] to evaluate the *in vivo* strain while the patient was performing some rehabilitation exercises (step and cycling), but exercises such as ascending and descending stairs, walking or jumping have not been considered. Finally, experiments with motion capture in combination with biplanar fluoroscopy [8, 9] have been performed to estimate ACL length and strain during walking and jumping but we do not have data for activities such as climbing stairs, running or crossover cutting.

In our opinion, create a reliable and easy to implement methodology to estimate *in vivo* ACL strain and forces capable of being applied in all kinds of activities, would help us not only to design better ligament implants but to prevent injury risks, improve rehabilitation protocols, study graft insertion points in order to reduce failure rates, or design ligaments according to patient's needs.

Therefore, in order to understand the behaviour of the ACL and design improved implants, it is necessary to study its kinematics and kinetics while both high impact maneuvers and daily living activities are performed. 78 % of the ACL injuries are due to noncontact activities and most of them happen on sudden deceleration, while landing from a jump, with cross-over cutting or pivoting [10]. At this stage we have studied the strain and the forces imposed on the ligament while participants ascend and descend stairs; however activities such as walking, running, jumping and cross-over cutting will be performed in future experiments.

In future work, these forces will be used as boundary conditions in our novel Finite Element Model to estimate the tensile and shear stress on the ligament and on our implant at all range of motion and for different activities, to enable comparison and assess our design.

The aim of this early stage of the project is to develop a methodology, applicable in all kind of activities, in order to determine the *in vivo* forces experienced by the ACL, with which we can design through a Finite Element Model improved ligament implants.

2. Methods

2.1. Recruitment of healthy participants

Nine subjects (6 men and 3 women; mean±SD age: 41.4±13years, height: 1.7±0.09 m and mass: 69.3±13.7 kg) were recruited in this study. Each participant was asked to sign a consent form and to complete two questionnaires prior beginning any activity. The questionnaires were the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Hip

Injury and Osteoarthritis Outcome Score (HOOS), and they allow us to assess knee and hip pain/symptoms and to include in the study only the subjects with no history of knee injury, surgery or pain.

2.2. Motion capture

A total of 33 reflective markers were placed on each participant on specific anatomical landmarks of the lower and upper body. In addition, a set of 16 wireless surface electromyography (EMG) sensors (Delsys Inc. Boston, MA, USA) were situated on each subject, recording the activation of the muscles *quadriceps vastus medialis*, *quadriceps rectus femoris*, *quadriceps vastus lateralis*, *tibialis anterior*, *peroneus longus*, *gluteus medius*, *medial hamstrings* and *gastrocnemius medialis* of both legs. The purpose of EMG recordings was to validate the correct behaviour of the muscles in our musculoskeletal model.

Before starting the experiment the 10-camera motion capture system (Vicon 612 system, Oxford Metrics, UK) was calibrated in order to calculate the location and orientation of all the cameras, and the correct operation of the EMG electrodes was checked on each participant.

The experiments were performed over an 8-step experimental staircase. This staircase had standard dimensions and contained four force platforms (Kistler, Switzerland) embedded into the middle steps. The force plates were used to help inform the static optimization solver implemented in OpenSim with the calculation of the muscle activation. A first static trial for subject calibration (scale body segments and align joints) was performed with each subject. This first trial was considered successful when all markers were visualized. Then, the subjects were asked to ascend and descend the staircase at a normal self-selected speed in a step-over-step manner up to a total of three successful trials, while kinematic data were captured and EMG signal and reaction forces were recorder.

Once the data were collected, they were processed in Vicon Nexus 1.8.5. (Vicon Motion Systems Ltd, UK) software and exported to OpenSim 3.2 (Stanford University, Stanford, CA) for further analysis.

2.3. Determination of ACL elongation

A musculoskeletal model was developed based on a lower extremity with back and torso model created by the developers of OpenSim. This model consists of 23 degree of freedom, 12 elements representing the bones and 92 musculotendon actuators.

The anterior cruciate ligaments were added to this model. These were modelled as a nonlinear elastic passive soft tissue, following a straight line path and it was assumed that there was negligible ligament-bone contact. A Thelen2003 muscle [11] model implemented in OpenSim and based on Hill's model [12] was used to simulate the ACL. In order to mimic its passive character, the fibre length was set to zero and the contractile element activation was annulled.

The attachment sites were incorporate to this model using the average values reported in Xu et al. [13] and the placement was verified through Lee et al. [14] and Jordan et

al. [15]. The coordinates for femur and tibia insertion points are given in table 1.

Table 1. ACL insertion points

	Insertion at femur (m)			Insertion at tibia (m)		
	X	Y	Z	X	Y	Z
Right leg	-0.0111	-0.4051	0.00705	0.00955	-0.0313	-0.00035
Left leg	-0.0111	-0.4051	-0.00705	0.00955	-0.0313	0.00035

The two ACL fibre bundles (anteromedial and posterolateral) were not considered in this model, since it was demonstrated [16, 17] that the behaviour of both bundles is similar. Both bundles are stretched when the knee is extended and shortened when the knee is flexed. In addition, most surgeons prefer to perform a single bundle surgery to minimize loss of bone, risk of infection, time, and favour healing.

The ACL length was estimated from kinematic data. Since the OpenSim model allows to track the coordinates of the attachment sites and calculate the elongation at each moment with an analysis solver.

2.4. ACL force estimation

It is well known that ligaments have a viscoelastic character and follow a non-linear force/displacement curve due to the crimping pattern of their fibres. This study used the force/displacement curve defined by Blankevoort and Huiskes et al. [18] where a ligament was simulated by a non-linear spring. To this method a damping element in parallel was incorporated in order to mimic its viscoelastic behaviour.

The estimation of the tensile force exerted by the spring (F_1) was performed following the equations presented in [18]:

$$F_1 = \frac{1}{4} k \varepsilon^2 / \varepsilon_l \quad 0 \leq \varepsilon \leq 2 \varepsilon_l \quad (1)$$

$$F_1 = k (\varepsilon - \varepsilon_l) \quad \varepsilon > 2 \varepsilon_l \quad (2)$$

$$F_1 = 0 \quad \varepsilon < 0 \quad (3)$$

Where:

ε	Strain of the ligament
ε_l	Linear range threshold
k	Stiffness of the spring

The strain is calculated from the ligament length (L) at each position and the zero-load length (L_0).

$$\varepsilon = (L - L_0) / L_0 \quad (4)$$

The unloaded ligament length is difficult to know; therefore it was estimated by the length (L_r) and strain (ε_r) of the ligament at full extension, the reference position in our trials.

$$L_0 = L_r / (\varepsilon_r + 1) \quad (5)$$

The force exerted by the damper (F_2) was estimated following the equation (6):

$$F_2 = D v \quad (6)$$

Where:

D	Damping coefficient
v	Ligament velocity calculated by the central difference method.

The parameters to model the ligaments are shown in table 2.

Table 2. Stiffness, threshold strain, reference strain and damping coefficient.

k (N)	ε_l	ε_r	D (N s/m)
5000 [18]	0.03 [18]	0.08 [18]	500 [17,19]

2.5. Statistical analysis

No outliers in the data were observed from visual inspection.

Moreover, differences between estimated ACL forces on both knees for sex, age and activities groups were compared using a one-way analysis of variance (ANOVA) with a 95% confidence interval. All statistical analyses were conducted using SPSS (IBM Inc, Chicago, Illinois).

3. Results

The same pattern of knee flexion/extension angle and ACL length was observed for each participant. Since an 8-step staircase was used to perform the experiment, four cycles for each leg were obtained. This model showed that the length of the ACL increased when the knee was extended and decreased as flexion angle was increased regardless of the performed activity, this pattern is shown in figure 1. Analyzing the motion during climbing stairs, the maximum ACL length was recorded at knee full extension (stage A in figure 1). The first ACL length minimum was at 90 degrees of knee flexion (stage B), then the ACL length increased at peak knee flexion due to the position of the insertion points (stage C). The second ACL length minimum was recorded at full strike (stage D) and finally the length increased again at the stance phase.

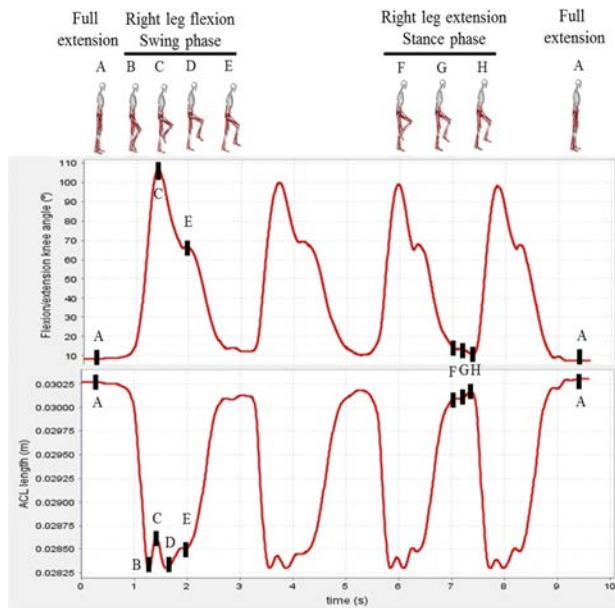


Fig. 1. Flexion knee angle (°) versus ACL length (m) ascending stairs.

The average of the maximum ACL length recorded was 0.0289 ± 0.0017 m corresponding to a full extension position and the average of the minimum ACL length was

0.027 ± 0.0016 m. Therefore, the maximum elongation recorded was 0.0019 ± 0.0001 m, which is about 19% of the reported elongation at failure of the ACL [20, 21].

Previous studies with 20 human cadaveric knees determined that the average of ACL length in men is 0.029 ± 0.0025 m and in women 0.0268 ± 0.0028 m [4], following these findings we can conclude that our ACL length estimations are within the same range and therefore they can be considered as anthropometrically valid.

Analyzing the strain, we observed a maximum strain of 0.084 ± 0.0047 and a minimum strain of 0.012 ± 0.0048 .

The maximum force experience by the ligament was observed at full extension of the knee. The average of the peak ACL force/body weight (BW) while the subject was ascending stairs was 0.409 ± 0.058 N/BW and descending stairs was 0.416 ± 0.089 N/BW. The peak ACL force was estimated to be 325.43 N for descending stairs, which is around 18% of the reported failure strength of the ligament [20, 21].

The most statistically significant values of force are shown in table 3. Moreover, the values of peak ACL strain and forces for men versus women and young versus adults are shown in tables 4 and 5.

Table 3. ACL forces during stair negotiation (mean \pm SD). ANOVAS for groups of sex, age and activities.

Total ACL force (N/BW)	Sex			Age			Activity		
	Men	Women	P value	Young (<40)	Older (>40)	P value	Ascending	Descending	P value
Right ACL	0.181 ± 0.131	0.248 ± 0.181	0.000	0.191 ± 0.141	0.217 ± 0.165	0.000	0.187 ± 0.149	0.217 ± 0.150	0.000
Left ACL	0.176 ± 0.135	0.251 ± 0.188	0.000	0.192 ± 0.143	0.208 ± 0.176	0.000	0.199 ± 0.153	0.197 ± 0.160	0.424

Table 4. Peak ACL strain and forces (mean \pm SD) during stair negotiation in men and women.

		Strain		Maximum Force/BW	
		Maximum	Minimum	Total Force (N/BW)	Damper Contribution Force (N/BW)
Ascending stairs	Men	0.085 ± 0.006	0.012 ± 0.005	0.383 ± 0.037	0.002 ± 0.0005
	Women	0.083 ± 0.001	0.012 ± 0.006	0.462 ± 0.061	0.003 ± 0.0007
Descending stairs	Men	0.084 ± 0.003	0.013 ± 0.005	0.375 ± 0.044	0.003 ± 0.0005
	Women	0.086 ± 0.007	0.015 ± 0.006	0.497 ± 0.109	0.004 ± 0.001

Table 5. Peak ACL strain and forces (mean \pm SD) during stair negotiation in young and older adults.

		Strain		Maximum Force/BW	
		Maximum	Minimum	Total Force (N/BW)	Damper Contribution Force (N/BW)
Ascending stairs	Young	0.081 ± 0.001	0.011 ± 0.005	0.415 ± 0.049	0.0025 ± 0.0004
	Older	0.088 ± 0.004	0.012 ± 0.006	0.403 ± 0.075	0.0024 ± 0.0009
Descending stairs	Young	0.081 ± 0.001	0.013 ± 0.004	0.416 ± 0.047	0.0036 ± 0.0012
	Older	0.089 ± 0.004	0.017 ± 0.003	0.416 ± 0.135	0.0033 ± 0.0009

4. Discussion

From table 3, 4 and 5 the following conclusions can be deduced. Women's anterior cruciate ligaments were subjected to significantly higher tensile forces compared to men's ACL and in general these forces were higher when the participant was descending stairs. This conclusion agrees with a previous study which reported that female athletes suffer ACL injuries from 4 to 6 more times than male athletes [22].

For this study and in order to determine how the age contribute to the ACL forces, the participants below 40 years old were considered as young people and the participants above 40 as aged people. The ANOVA test for the group of age showed that the ACL forces in both legs were highly significant for older people compared to young people. This phenomenon can be explained since the tissue lose water and get stiffer as we get older, therefore the ACL force are expected to be higher as we became older following Hooke's law, where the force is directly proportional to the stiffness.

To date there is no OpenSim model to estimate ACL force during stair negotiation. Therefore the values of ACL force obtained in this study are difficult to compare with other models. However, some studies reported that the peak ACL forces during gait are between 0.2 N/BW and 0.7 N/BW [23]. Our estimation was around 0.41 N/BW; therefore it was similar to the ACL loads previously reported.

The viscoelastic contribution in the force, quantified by the ACL velocity and the damping coefficient, was negligible compared to the ACL total force. Moreover, in neither case significant differences were observed after performing different analysis of variance.

Several studies have been done to determine the ACL length and strain based on motion capture and biplanar fluoroscopic images, while certain activities such as walking and jumping are performed [8, 9]. These studies reported a peak ACL strain of up to 13%. In our study the peak ACL strain was up to 8.9% descending stairs, therefore we can say that our model provides a realistic estimation of ACL strain.

Some limitations are associated to this methodology. First, we approximated the path of the ACL as a straight line in the OpenSim model. However, the fibre bundles of the ACL are twisted each other and wrapped around the bones. Therefore, the calculation of the length and ligament force is affected by this approximation. In addition, the ligament-bone contact was neglected following Blankevoort and Huiskes et al. [18].

Second, the unloaded length of the ACL is unknown and it was estimated from reference lengths and strains. However, the insertion points and the reference length are different from one person to other. Although the reference length was changed for each participant, we considered the same attachment points for all our subjects. These differences could generate an error in our estimation of ACL forces.

Finally, the ACL length and force was compared with knee flexion angles, in order to compare these values with *varus/valgus* angle and rotation angle a 6 degree of freedom model of the knee must be performed.

In conclusion, we have established a methodology to estimate *in vivo* tensile forces on the ACL during different dynamic activities. These forces will be considered as boundary conditions in a future finite element model to enable estimation of tensile and shear stress on the ACL and on our implant. Finally, we have proved that the force experienced by the ACL in women and in age people is highly significant compared to men and young people respectively.

We consider this work relevant to be presented at the CIRP-Biomanufacturing conference, since our project aims to understand the mechanical behaviour of ACL throughout its range of motion with the purpose of being the starting point for the design and manufacture of new ACL implants.

Conflict of interest statement

There are no conflicts of interest in this work.

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